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| EXAMINER | |
|---|---|
| KALINOWSKI, ALEXANDER G | |
| ART UNIT | PAPER NUMBER |
| 3626 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/923,385 | Applicant(s) Michelson et al. |
|---|---|---|
| | Examiner Alexander Kalinowski | Art Unit 3626 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Mar 11, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *2-15 and 129-151* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *2-15 and 129-151* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

1. Claims 2-15 and 129-151 are presented for examination. Applicant filed a petition to make special on 8/8/2001. The petition to make special was granted on 8/12/2002. Of originally filed claims 1-15 and 121-128, Applicant filed an amendment on 3/11/2003, canceling claims 1 and 121-128, amending claims 2-5, 7-13 and 15 and adding new claims 129-152. After careful consideration of Applicant's amendment's and arguments, the Examiner finds Applicant's arguments nonpersuasive and maintains the rejection of claims 2-15 and new grounds of rejection are established for claims 129-151. Therefore, the instant office action is a final rejection of claims 2-15 and 129-151 as set forth in detail below.

### *Response to Arguments*

2. With respect to the objection to the declaration, Applicant's argument is persuasive, therefore, the Examiner withdraws the objection to the declaration.

3. With respect to the rejection of claim 4 based on 35 USC 112(2), in light of Applicant's amendment to claim 4, the Examiner withdraws the rejection.

4. With respect to Applicant's argument that the CenterWatch reference is not prior art, Applicant argues that the publication date of the CenterWatch article is the date of the printouts, namely, 11/2002 and 12/2002. The Examiner disagrees. The Examiner notes that the web pages were generated using the Internet Archives. The Examiner further notes that the Examiner is supplying a hardcopy of instructions found at the Internet Archive web site on how to determine

the publication date of the web pages found using the Internet Archives. The publication date of the CenterWatch reference is from 5/7/1998 through 12/5/1998. Clearly, even applying the latest publication date of the CenterWatch printout of 12/5/1998, the reference qualifies as prior art with respect to the instant application. Therefore, Applicant's argument is nonpersuasive.

Applicant further argues that the cited portion of the Colon reference used to establish motivation to combine the teachings of Colon with the CenterWatch reference cannot be proper motivation since the statement was found in the summary of the invention section of the patent. The Examiner disagrees. As discussed in MPEP 608.01(d), the summary of the invention apprises the public and those of ordinary skill in the art the nature of the invention and to the specific invention being claimed. In other words, the summary contains an explanation of the invention and may include a statement of benefits or advantages. Indeed, the whole point of an invention is to improve on the prior art. Furthermore, motivation can be found anywhere within a cited reference and is not limited to specific sections of a patent publication. Therefore, Applicant's argument is nonpersuasive.

Applicant also argues that even one of ordinary skill in the art would have been motivated to from Colon's summary as cited by the Examiner, this does not indicate a motivation to do so using the particular system described by CenterWatch and that it is well established that for two art references to be combined and used to render an invention obvious, there must be some motivation to combine them.. The Examiner disagrees. The Examiner cited motivation to combine the teachings of Colon with CenterWatch directly from the Colon reference (see MPEP 2143.01).

The Examiner cited the motivation to combine the references directly from the secondary reference (Colon). Therefore, Applicant's argument is nonpersuasive.

Finally, Applicant argues that the combination of Colon and CenterWatch is improper for the reason that the database of Colon would be inoperable with the CenterWatch system without modification being made to it or if altered and properly combined, that the Colon database would be inoperable for its originally stated purpose. The Examiner disagrees. The Examiner notes that the claims are directed to a method and not an apparatus. Therefore, the Examiner's use of Colon is for a disclosure as to the method of using. The Examiner use of the Colon database was merely to disclose the use of permitting a user to register with a database. Since CenterWatch did not explicitly state the use of a database with the step of registering, the Examiner cited the Colon reference as evidence that databases may be used for registration purposes. The disclosure of Colon teaches the use of a database for registering patients. Applicant's arguments directed to bodily incorporating the database of Colon or modifying the database of Colon simply do not apply to a situation where the claims are directed to a method of recruiting patients. In other words, the teachings of Colon are not being used to disclose system components, such as a specific type of database, that is combined with the system of CenterWatch. It is the method of Colon that is being combined with the method CenterWatch. Furthermore, the prior art described the desirability of this feature as shown in the motivation cited directly from Colon. Therefore, Applicant's arguments that the Colon and CenterWatch combination is improper is nonpersuasive.

Applicant further argues that Colon and CenterWatch do not disclose in amended claim 2 the step of

(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d).

The Examiner disagrees. The Examiner used the Colon reference to disclose this feature of (e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d). Applicant argues that Colon does not provide notice of a particular study. The Examiner notes that the CenterWatch reference was used to disclose this feature. The Examiner did not rely on Colon to disclose providing notice of a particular study. Furthermore, Applicant acknowledges that Colon discloses that followup information is entered into a database. A careful reading of Colon discloses that the Colon method "captures data in its database through appropriate input forms developed for the specific clinical study (see col. 1, lines 64-67). Clearly, the Colon method provides forms for user input that is to be entered into the database. The forms provide instructions (i.e. questionnaire) for the user to input information required by the clinical study. Therefore, Colon discloses automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d) and Applicant's arguments are nonpersuasive as to amended claim 2.

Applicant further argues limitations in newly added claims 138, 139, 150, 140, 149, and 151. The Examiner directs the Applicant to the detailed grounds of rejection of these newly added claims as set forth in the next section below.

With respect to claim 3, Applicant argues that CenterWatch and Colon do not disclose (g) accessing the information stored along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f)

The Examiner notes that the Applicant argues the newly added limitation of "the use of responses to a questionnaire along with other information in the database ...". This feature was not present in claim 3 or any of the other originally filed claims. Therefore, the Examiner refers the Applicant to the detailed rejection of claim 3 in the next section below.

With respect to claim 4, Applicant argues that Colon does not disclose

wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study

The Examiner disagrees. The Examiner notes that the cited passage in Colon (col. 7, lines 8-37) includes a description of an application program "performing a test to see if the patient meets a control parameter for the study". Clearly, this test determines whether the patient is an eligible subject for the study. Therefore, Applicant's argument is nonpersuasive.

With respect to claim 5, Applicant argues that Colon does not disclose where

step (d) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site. The Examiner disagrees. Clearly, Colon discloses performing an eligibility test after data is sent to the server and then returning a message of ineligibility if the answer is no and the procedure is terminated or if the

answer is yes, assigns the patient to one of the studies and sends a suggested drug prescription (col. 6, lines 39-57) . Clearly, the person or caregiver is notified of the given clinical study during a current or subsequent visit. Furthermore, Applicant's statement that user of the database is the physician further reinforces the Examiner's position since the physician is the caregiver. Therefore, Applicant's arguments are nonpersuasive.

With respect to claims 8 and 9, Applicant noted that the Examiner stated that Colon and CenterWatch do not explicitly disclose

wherein the notice provided in step (d) is sent by regular mail to the person or caregiver

wherein the notice provided in step (d) is communicated by telephone to the person or caregiver

Applicant further argued that the Examiner used official notice and argues that the Examiner did not indicate why it would have been obvious to use regular mail or telephone for a transaction that is otherwise completely electronic. The Examiner disagrees. Applicant asserts that convenience dictates that the correpondance take place electronically and not take place using regular mail or telephone. Clearly this is speculative on the part of Applicant. Convenience dictates that correspondence takes place using the method of communication preferred by the patient or caregiver (i.e. convenience of the user). If for no other reason, the person is more likely to use a system that is more user friendly than one that is less so. Furthermore, communication by mail and telephone reduce costs incurred by the user of the electronic system since the user may log off the system thereby reducing costs associated with being logging into to the system. Therefore, Applicant's arguments are nonpersuasive.

With respect to claim 11, Applicant argues that the Examiner has not indicated where in CenterWatch a determination is made not to provide the person with notice of the given clinical study. The Examiner disagrees. The Examiner cited the passage in CenterWatch including the page number that discloses this limitation (see page 9, Paper No. 10). Furthermore, the cited passage of "would like to be notified by e-mail of future trial postings to this site in a particular therapeutic area ..." surely discloses notifying the patient of the given clinical study in a particular area. However, this also means that the patient will not be notified of the given study for other therapeutic areas that are different from the particular therapeutic area. Therefore, Applicant's arguments are nonpersuasive.

With respect to claim 12, Applicant amended claim 12 as referenced in Applicant's arguments and the Examiner refers the Applicant to the detailed grounds of rejection of claim 12 in the next section below.

With respect to claims 6, 13, 14, and 15, Applicant argues that CenterWatch and Colon do not disclose any of the claims from which claims 6, 13, 14, and 15 depend. The Examiner disagrees. As stated in response to Applicant's arguments above, CenterWatch and Colon do teach the claims from which claims 6, 13, 14, and 15 depend.. Therefore, Applicant's argument is nonpersuasive.

With respect to claim 6, Applicant argues that Clinmark does not disclose

step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site.

The Examiner disagrees. Clinmark discloses an internet-based database of clinical trial information, specifically related to clinical trial investigators (see abstract). Therefore, Clinmark discloses a listing of information associated with the given clinical study with the person or caregiver on the web site. Furthermore, the electronic bulletin boards of the web site provides topical information to those interested individuals and functions as a personal library associated with the person or caregiver on the web site. Therefore, Applicant's arguments are nonpersuasive.

Applicant further argues that there is not motivation to combine Clinmark with CenterWatch and Colon. The Examiner disagrees. Motivation to combine Clinmark with CenterWatch and Colon was cited directly in Clinmark. Furthermore, it appears that Applicant is arguing that CenterWatch does not recognize a need for the disclosure of Clinmark. Again, the Examiner points to the Clinmark reference as providing the motivation for combining the teachings of Clinmark with CenterWatch and Colon. Therefore, Applicant's arguments are nonpersuasive.

With respect to claim 13, Applicant argues that Clinmark does not explicitly disclose wherein a determination is made to provide the person or caregiver with the notice in step c in accordance with a geographic location of an investigator associated with the study. The Examiner disagrees. Applicant argues that the passage in Clinmark cited by the Examiner was discussing a director of clinical affairs searching for oncologist not a person or caregiver looking to participate in a clinical study. It seems that Applicant is asserting that the identity of the user somehow changes the claimed method of 13. The Examiner used the Clinmark to disclose a method of

providing notice in accordance with a geographic of an investigator associated with the study. The Examiner used Colon and CenterWatch to disclose providing notice to a person or caregiver of a given clinical study. Therefore, the combination of Colon, CenterWatch and Clinmark disclose the limitation of "wherein a determination is made to provide the person or caregiver with the notice in step c in accordance with a geographic location of an investigator associated with the study" and Applicant's arguments are nonpersuasive.

With respect to claim 14, Applicant argues that Clinmark does not disclose

wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources. .Furthermore Applicant argues that Clinmark does not teach persons or caregivers searching for clinical studies. The Examiner disagrees. The Examiner used Colon and CenterWatch to disclose persons or caregivers searching for clinical studies. The Examiner use of the Clinmark reference was to show non electronic communication means (i.e. telephone can be used instead of computer to submit clinical studies related or associated information) The combination of Colon, CenterWatch and Clinmark disclose wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources. Therefore, Applicant's arguments are nonpersuasive.

With respect to claim 15, Applicant argued that Larkin does not disclose wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database. The Examiner disagrees. The passage cited in Larkin clearly discloses using the web to recruit for a gene discovery program.

Presumably, gene sequence information would be used to determine patient eligibility for a gene discovery program. The combination of CenterWatch, Colon and Larkin disclose wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database and Applicant's arguments are nonpersuasive.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-5, 7-12 and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over information published at www.centerwatch.com (hereinafter CenterWatch) in view of Colon et al., Pat No. 5,991,731 (hereinafter Colon).

As to claim 2, CenterWatch discloses a method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a web site by submitting registration information to the web site, wherein the registration information includes at least a geographic location of the person, at least one disease condition of interest to the person, contact information, and permission information

indicating whether the person or caregiver wishes to receive notice of one or more clinical studies (i.e. Patient Notification Service web pages, email address, therapeutic areas, geographic regions, address, "unsubscribe")(Patient Notification Service, pages 1-3);

(b) automatically registering the person or caregiver with the web site upon receipt of the registration and permission information (i.e. if you're a patient or patient advocate seeking information about clinical trials ... then sign up here)(CenterWatch Clinical Trials Listing Service Home Page, page 1);

c after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person (i.e. would like to be notified by e-mail of future trial postings to this site in a particular therapeutic area ...)(CenterWatch Clinical Trials Listing Service Home Page, page 1); and

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step c to provide such notice (i.e. would like to be notified by e-mail of future trial postings to this site in a particular therapeutic area ...)(CenterWatch Clinical Trials Listing Service Home Page, page 1).

CenterWatch does not explicitly disclose

allowing the person or caregiver to register with a database.

However, Colon discloses allowing the person or caregiver to register with a database (i.e. computing center 10 has a database host computer 11 ... patient data is entered relating to

identification, demographics, and medical conditions ... after data is sent to the study management center 10, server computer executes a test to see if patient meets eligibility parameters for the study ...)(col. 1, lines 58-63 and col. 6, lines 22-52). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include allowing the person or caregiver to register with a database as disclosed by Colon within the CenterWatch method for the motivation of automatically assigning thousands of participants in a clinical study with respect to care strategies to be administered to study participants (col. 1, lines 42-51).

CenterWatch does not explicitly disclose

(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and

(f) storing answers submitted by the person or caregiver in the database.

However, Colon discloses (e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and (f) storing answers submitted by the person or caregiver in the database (i.e. the study will also include followup visits and the operation of the system for these consultations with a physician at participating sites ... followup data, endpoint data and significant events data is entered and after verification is transmitted through the Internet server 13 to the database host computer 11 for input to tables 51, 52, 53.)(col. 7, lines 8-37). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include (e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and(f) storing answers submitted

by the person or caregiver in the database as disclosed by Colon within the CenterWatch method for the motivation of automatically assigning thousands of participants in a clinical study with respect to care strategies to be administered to study participants (col. 1, lines 42-51).

As to claim 4, CenterWatch does not explicitly disclose the method of claim 2, wherein the questionnaire includes criteria specific to the clinical study for determining whether the person is an eligible subject for the given clinical study.

However, Colon discloses the questionnaire includes criteria specified by a sponsor of the clinical study for determining whether the person is an eligible subject for the given clinical study (i.e. the study will also include followup visits and the operation of the system for these consultations with a physician at participating sites ... followup data, endpoint data and significant events data is entered and after verification is transmitted through the Internet server 13 to the database host computer 11 for input to tables 51, 52, 53.)(col. 7, lines 8-37). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the questionnaire includes criteria specific to the clinical study for determining whether the person is an eligible subject for the given clinical study as disclosed by Colon within the CenterWatch method for the motivation of automatically assigning thousands of participants in a clinical study with respect to care strategies to be administered to study participants (col. 1, lines 42-51).

As to claim 5, CenterWatch discloses the method of claim l, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages (i.e. if you're a patient or patient advocate seeking information about clinical trials ... then sign up here)(CenterWatch Clinical Trials Listing Service Home Page, page 1).

CenterWatch does not explicitly disclose

where step (d) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site.

However, Colon discloses step (d) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site (col. 6, lines 39-50). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include where step (d) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site as disclosed by Colon within the CenterWatch method for the motivation of automatically assigning thousands of participants in a clinical study with respect to care strategies to be administered to study participants while the patient is in the doctor's office(col. 1, lines 42-51).

As to claim 7, CenterWatch discloses the method of claim 2, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver (i.e. would like to be notified by e-mail of future trial

postings to this site in a particular therapeutic area ...)(CenterWatch Clinical Trials Listing Service Home Page, page 1).

As to claim 8, CenterWatch and Colon do not explicitly disclose the method of claim 2, wherein the notice provided in step (d) is sent by regular mail to the person or caregiver.

However, the Examiner takes official notice that it was well known in the electronic arts to send requested notice information via mail. The motivation for delivering notice by regular mail is for the convenience of the requestor. It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include the notice provided in step (d) is sent by regular mail to the person or caregiver within the CenterWatch and Colon combination for the motivation stated above.

As to claim 9, CenterWatch and Colon do not explicitly disclose the method of claim 2, wherein the notice provided in step (d) is communicated by telephone to the person or caregiver.

However, the Examiner takes official notice that it was well known in the electronic arts to send notice information by telephone to a requestor. The motivation for delivering notice by telephone is for the convenience of the requestor. It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include the notice provided in step (d) is communicated by telephone to the person or caregiver within the CenterWatch and Colon combination for the motivation stated above.

As to claim 10, CenterWatch discloses the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step © in accordance with a geographic location of the given clinical study (i.e. Patient Notification Service web pages, email address, therapeutic areas, geographic regions, address, "unsubscribe")(Patient Notification Service, pages 1-3.

As to claim 11, CenterWatch discloses the method of claim 2, wherein in step © a determination is made not to provide the person or caregiver with notice of the given clinical study (i.e. would like to be notified by e-mail of future trial postings to this site in a particular therapeutic area ...)(CenterWatch Clinical Trials Listing Service Home Page, page 1).

As to claim 12, CenterWatch discloses the method of claim 2, wherein in step (a) the registration information includes whether the person is interested in clinical study information, whether the person is interested in new medical therapies, or whether the person is interested in participating in clinical studies (i.e. Patient Notification Service web pages, patient seeking clinical trial information ... therapeutic areas of interest)(Patient Notification Service, pages 1-3) .

As to Claim 129, CenterWatch discloses a method for recruiting a person to participate as a subject in a clinical study, comprising:

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a web site by submitting registration information to the web page wherein said information comprises a geographic location of the person, a therapeutic area, disease, or condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies (i.e. Patient Notification Service web pages, email address, therapeutic areas, geographic regions, address, "unsubscribe")(Patient Notification Service, pages 1-3);

(b) registering automatically the person or caregiver with the web site upon receipt of the registration information (i.e. if you're a patient or patient advocate seeking information about clinical trials ... then sign up here)(CenterWatch Clinical Trials Listing Service Home Page, page 1);

c) after step b) determining automatically in accordance with the registration information whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person (i.e. would like to be notified by e-mail of future trial postings to this site in a particular therapeutic area ...)(CenterWatch Clinical Trials Listing Service Home Page, page 1); and

(d) providing the person or caregiver with notice of the given clinical study only if a determination is made to provide such notice (i.e. would like to be notified by e-mail of future trial postings to this site in a particular therapeutic area ...)(CenterWatch Clinical Trials Listing Service Home Page, page 1).

(e) allowing the person or caregiver the opportunity to amend the registration information during a subsequent visit to the web site (i.e. please note that if you plan to add illness areas at any time in the future, make sure to re-enter all previous selections of interest ...)(CenterWatch Patient Notification Service, page 1).

CenterWatch does not explicitly disclose

allowing the person or caregiver to register with a database.

However, Colon discloses allowing the person or caregiver to register with a database (i.e. computing center 10 has a database host computer 11 ... patient data is entered relating to identification, demographics, and medical conditions ... after data is sent to the study management center 10, server computer executes a test to see if patient meets eligibility parameters for the study ...)(col. 1, lines 58-63 and col. 6, lines 22-52). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include allowing the person or caregiver to register with a database as disclosed by Colon within the CenterWatch method for the motivation of automatically assigning thousands of participants in a clinical study with respect to care strategies to be administered to study participants (col. 1, lines 42-51).

7. Claims 3 and 130-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over CenterWatch inn view of Colon as applied to claim 2 above, and further in view of "drkoop.com & Quintiles Launch service to recruit Clinical Trial Patients on the Internet" (hereinafter drkoop).

As to claim 130, CenterWatch and Colon do not explicitly disclose the method of claim 2, wherein said questionnaire is a pre-examination questionnaire

However, drkoop discloses said questionnaire is a pre-examination questionnaire (i.e. interactive questionnaire to pre-screen potential participants)(page 2, lines 18-26). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include wherein said questionnaire is a pre-examination questionnaire as disclosed by drkoop within CenterWatch and Colon for the motivation of increasing the likelihood that patients referred to a site are qualified to participate in the trial (page 2, lines 27-29).

As to claim 131, CenterWatch and Colon do not explicitly disclose the method of claim 130, wherein said pre-examination questionnaire is a screening questionnaire

However, drkoop discloses said pre-examination questionnaire is a screening questionnaire (i.e. interactive questionnaire to pre-screen potential participants)(page 2, lines 18-26). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include wherein said pre-examination questionnaire is a screening questionnaire as disclosed by drkoop within CenterWatch and Colon for the motivation of increasing the likelihood that patients referred to a site are qualified to participate in the trial (page 2, lines 27-29).

As to claim 132, CenterWatch and Colon do not explicitly disclose the method of claim 130, wherein said pre-examination questionnaire is a pre-screening questionnaire

However, drkoop discloses said pre-examination questionnaire is a pre-screening questionnaire (i.e. interactive questionnaire to pre-screen potential participants)(page 2, lines 18-26). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include wherein said questionnaire is a pre-examination questionnaire as disclosed by drkoop within CenterWatch and Colon for the motivation of increasing the likelihood that patients referred to a site are qualified to participate in the trial (page 2, lines 27-29).

As to claim 133, CenterWatch and Colon do not explicitly disclose the method of claim 2, wherein said questionnaire is a pre-screening questionnaire

However, drkoop discloses said questionnaire is a pre-screening questionnaire (i.e. interactive questionnaire to pre-screen potential participants)(page 2, lines 18-26). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include wherein said questionnaire is a pre-screening questionnaire as disclosed by drkoop within CenterWatch and Colon for the motivation of increasing the likelihood that patients referred to a site are qualified to participate in the trial (page 2, lines 27-29).

As to claim 134, CenterWatch and Colon do not explicitly disclose the method of claim 2, wherein said questionnaire is a screening questionnaire

However, drkoop discloses said questionnaire is a screening questionnaire (i.e. interactive questionnaire to pre-screen potential participants)(page 2, lines 18-26). It would have been

obvious to one of ordinary skill int eh art at the time of Applicant's invention to include wherein said questionnaire is a screening questionnaire as disclosed by drkoop within CenterWatch and Colon for the motivation of increasing the likelihood that patients referred to a site are qualified to participate in the trial (page 2, lines 27-29).

As to claim 135, CenterWatch and Colon do not explicitly disclose the method of claim 134, wherein said screening questionnaire is protocol specific.

However, drkoop discloses said screening questionnaire is protocol specific(i.e. interactive questionnaire to pre-screen potential participants ... responses are evaluated to determine if they meet the trial's basic criteria. ...)(page 2, lines 18-26). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include wherein said questionnaire is a screening questionnaire as disclosed by drkoop within CenterWatch and Colon for the motivation of increasing the likelihood that patients referred to a site are qualified to participate in the trial (page 2, lines 27-29).

As to claim 136, CenterWatch and Colon do not explicitly disclose the method of claim 2, wherein said questionnaire is designed for screening for clinically appropriate persons..

However, drkoop discloses said questionnaire is designed for screening for clinically appropriate persons (i.e. interactive questionnaire to pre-screen potential participants ... responses are evaluated to determine if they meet the trial's basic criteria. ...)(page 2, lines 18-26). It would

have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include said questionnaire is designed for screening for clinically appropriate persons as disclosed by drkoop within CenterWatch and Colon for the motivation of increasing the likelihood that patients referred to a site are qualified to participate in the trial (page 2, lines 27-29).

As to claim 137, CenterWatch and Colon do not explicitly disclose the method of claim 2, wherein said questionnaire requests information regarding inclusion/exclusion criteria

However, drkoop discloses said questionnaire requests information regarding inclusion/exclusion criteria (i.e. interactive questionnaire to pre-screen potential participants ... responses are evaluated to determine if they meet the trial's basic criteria. ...)(page 2, lines 18-26). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include said questionnaire requests information regarding inclusion/exclusion criteria as disclosed by drkoop within CenterWatch and Colon for the motivation of increasing the likelihood that patients referred to a site are qualified to participate in the trial (page 2, lines 27-29).

As to claim 3, CenterWatch and Colon do not explicitly disclose the method of claim 2, further comprising the step of

(g) accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f).

However, drkoop discloses accessing the answers to the questionnaire along with other information to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f )(i.e. individuals who do not fit a trial's inclusion criteria ... can consent to have their pre-screening information stored in a database and matched with appropriate trials in the future)(page 2, lines 18-38). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f) as disclosed by drkoop within CenterWatch and Colon for the motivation of to assisting patents to participate in a clinical trial (page 2, lines 18-38).

8. Claims 138-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over CenterWatch in view of Colon and drkoop.

As to Claim 138, CenterWatch discloses a method for recruiting a person to participate as a subject in a clinical study, comprising:

(a) presenting at least one web page to permit an individual to be registered by indicating whether the individual wishes to receive notice of one or more clinical studies and registration information, wherein said registration information includes at least a geographic location of the person, a disease condition of interest to the person, and contact information (i.e. Patient Notification

Service web pages, email address, therapeutic areas, geographic regions, address, "unsubscribe")(Patient Notification Service, pages 1-3);

(b) automatically registering the individual with the database upon receipt of the registration and indicating information (i.e. click on sign up to register)(CenterWatch patient Notification Service, pages 1-3);

c) after step b) determining automatically in accordance with the indicating information and the registration information, whether to provide the individual or caregiver with notice of a given clinical study associated with the disease condition (i.e. would like to be notified by e-mail of future trial postings to this site in a particular therapeutic area ...)(CenterWatch Clinical Trials Listing Service Home Page, page 1); and

(d) providing the individual notice of the given clinical study (i.e. would like to be notified by e-mail of future trial postings to this site in a particular therapeutic area ...)(CenterWatch Clinical Trials Listing Service Home Page, page 1).

CenterWatch does not explicitly disclose

allowing the individual to register with a database.

However, Colon discloses allowing the individual to register with a database (i.e. computing center 10 has a database host computer 11 ... patient data is entered relating to identification, demographics, and medical conditions ... after data is sent to the study management center 10, server computer executes a test to see if patient meets eligibility parameters for the study ...)(col. 1, lines 58-63 and col. 6, lines 22-52). It would have been obvious to one of ordinary skill int eh

art at the time of Applicant's invention to include allowing the individual to register with a database as disclosed by Colon within the CenterWatch method for the motivation of automatically assigning thousands of participants in a clinical study with respect to care strategies to be administered to study participants (col. 1, lines 42-51).

CenterWatch and Colon do not explicitly disclose

e) presenting a screening questionnaire associated with the clinical study; and

f) storing answers submitted by the individual in the database.

However, drkoop discloses presenting a screening questionnaire associated with the clinical study (i.e. interactive questionnaire to pre-screen potential participants ... responses are evaluated to determine if they meet the trial's basic criteria. ...)(page 2, lines 18-26). drkoop further discloses storing answers submitted by the individual (page 2, lines 18-26). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include presenting a screening questionnaire associated with the clinical study and storing answers submitted by the individual as disclosed by drkoop within CenterWatch and Colon for the motivation of increasing the likelihood that patients referred to a site are qualified to participate in the trial (page 2, lines 27-29).

As to claim 139 and 140, the claims are similar in scope to claim 138 and are rejected on the same basis.

As to claims 141-148, the claims are similar in scope to claims 130-137 and are rejected on the same basis.

As to claims 149-151, the claims are similar in scope to claim 138 and are rejected on the same basis.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over CenterWatch and Colon as applied to claim 5 above, and further in view of "Pharmaceutical industry Embraces Clinmark Dotcom" (hereinafter Clinmark).

As to claim 6, CenterWatch and Colon do not explicitly disclose the method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site.

However, Clinmark discloses step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site (i.e. electronic bulletin boards)(page 2). It would have been obvious to one of ordinary skill int eh art at the time of Applicant's invention to include step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site as disclosed by Clinmark within the CenterWatch and Colon method for the motivation of providing a forum for individuals with a common purpose to learn about trends and exchange information (page 2)

10. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over CenterWatch and Colon as applied to claim 2 above, and further in view of Clinmark.

As to claim 13, CenterWatch and Colon do not explicitly disclose the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step © in accordance with a geographic location of an investigator associated with the study.

However, Clinmark discloses a determination is made to provide the person or caregiver with the notice in step © in accordance with a geographic location of an investigator associated with the study (i.e. ... searched for oncologist in the United States ...)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include

As to claim 14, CenterWatch and Colon do not explicitly disclose the method of claim 2, wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources.

However, Clinmark discloses the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources (i.e. Registration is available at ... 888-CLINMAR)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources as

disclosed by Clinmark within the CenterWatch and Colon method for the motivation of providing information in a convenient manner for the requestor.

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over CenterWatch and Colon as applied to claim 2 above, and further in view of Larkin, Marilynn, "Where to find clinical trials on the Web"(hereinafter Larkin).

As to claim 15, CenterWatch and Colon do not explicitly disclose the method of claim 2, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database.

However, Larkin discloses the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database (i.e. ... uses the web to recruit for its international gene discovery project)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include reference to genetic sequence information associated with a person registered in the database as disclosed by Larkin within the CenterWatch and Colon combination for the motivation of learning about trials in specific diseases (page 2).

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander Kalinowski, whose telephone number is (703) 305-2398. The examiner can normally be reached on Monday to Thursday from 9:00 AM to 6:30 PM. In addition, the examiner can be reached on alternate Fridays.

If any attempt to reached the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached on (703) 305-9588. The fax telephone number for this group is (703) 305-7687 (for official communications including After Final communications labeled "Box AF").

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor, receptionist.

Alexander Kalinowski

Patent Examiner

Art Unit 3626

June 1, 2003

# Recent Statutory Changes to 35 U.S.C. § 102(e)

On November 2, 2002, President Bush signed the 21st Century Department of Justice Appropriations Authorization Act (H.R. 2215) (Pub. L. 107-273, 116 Stat. 1758 (2002)), which further amended 35 U.S.C. § 102(e), as revised by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)). The revised provisions in 35 U.S.C. § 102(e) are completely retroactive and effective immediately for all applications being examined or patents being reexamined. Until all of the Office's automated systems are updated to reflect the revised statute, citation to the revised statute in Office actions is provided by this attachment. This attachment also substitutes for any citation of the text of 35 U.S.C. § 102(e), if made, in the attached Office action.

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

> **A person shall be entitled to a patent unless –**
>
> **(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.**

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 prior to the amendment by the AIPA that forms the basis for the rejections under this section made in the attached Office action:

> **A person shall be entitled to a patent unless –**
>
> **(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.**

For more information on revised 35 U.S.C. § 102(e) visit the USPTO website at www.uspto.gov or call the Office of Patent Legal Administration at (703) 305-1622.